REMARKS

Claims 1-44 were pending in this application. Claim 16 is now cancelled without prejudice to Applicants' right to prosecute the subject matter in the present application and in related applications. Claims 14, 15, 20-22 and 27-44 are withdrawn. New claims 45-48 are added and claims 1, 2, 6, 17 and 23 are currently amended without any intent of disclaiming equivalents thereof. Accordingly, claims 1-11, 17-24, and 45-48 are pending and presented for consideration.

According to the Examiner, withdrawn claims 14, 15 and 27-44 are drawn to non-elected invention. However, as the Examiner also indicated in the Office action of October 15, 2004, page 6, Applicants understand that upon allowance of the elected product claims, the related process claims, at least including claims 14, 15 and 27-44, will be rejoined in accordance with MPEP § 821.04. Withdrawn claims 20-22 are drawn to non-elected species. Applicants understand that upon allowance of generic claims corresponding to the elected species, Applicants may claim additional species as provided by 37 C.F.R. § 1.141.

Claim Amendments

Support for amendments to claims 1, 2 and 6 is found in original claims 1, 2 and 6, respectively. Claim 17 is rewritten in independent form. Support for amendment to claim 23 is found in the specification at least, for example, at page 4, paragraph 15. Support for new claims 45 and 46 is found in the specification at least, for example, at page 7, paragraph 29. Support for new claims 47 and 48 is found in the specification at least, for example, at page 12, paragraph 44.

Applicants submit that the amendments to the claims introduce no new matter.

Amendments to Specification

Applicants have amended the specification to correct a typographical error in paragraph 29. Support for the amendment is found in the specification, for example, in paragraph 27. In addition, Applicants have amended the specification to delete the number "2722168" as requested by the Examiner.

Drawings

Applicants thank the Examiner for clarifying the objection to the drawings during the telephonic interview on August 1, 2005. As the Examiner indicated during the interview, the objection should not apply to the present application, and Figures 2A-G and 3A-B can remain in the application.

Claim rejections under 35 U.S.C. § 112, first paragraph, enablement

Claims 1-11, 16-19, 23 and 24 stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the scope of the claims is allegedly not commensurate with the scope of the enabling disclosure. Applicants traverse this rejection to the extent it is maintained over the claims as amended.

The test for enablement is whether one reasonably skilled in the art could make or use the invention as broadly as it is claimed based on the disclosures in the specification coupled with information known in the art without undue experimentation.

Applying this test to the instant application, Applicants submit that the specification fully enables the invention as claimed in the claims as amended. Specifically, amended independent claim 1 recites "[a]n antibody variable region comprising the amino acid sequence set forth in SEQ ID NO:1." Amended independent claim 2 recites "[a]n antibody variable region comprising the amino acid sequence set forth in SEQ ID NO:2." Amended independent claim 6 recites "[a]n antibody variable region comprising an amino acid sequence selected from the group consisting of amino acids 1-23 of SEQ ID NO:1, amino acids 1-25 of SEQ ID NO:2, and amino acids 67-98 of SEQ ID NO:2." As set forth on pages 14-16, paragraphs 53-60, the specification of the present application provides sufficient guidance on how to make antibody constructs of the present invention. In addition, methods and tools for making an antibody variable region with a known sequence were well known and available to any one of ordinary skill in the art when this application was filed. Therefore, Applicants respectfully submit that the specification is sufficient to enable one of ordinary skill in the art to practice the claimed invention without undue experimentation. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

In addition, the Office action alleges that previously pending claims 16 and 23 read on fusion proteins comprising any non-immunoglobulin molecule, such as glucose, therefore, one of skill in the art would not know how to use the present invention. Without acquiescing to the rejection, and solely to advance prosecution, Applicants have cancelled claim 16 without prejudice and amended claim 23 to replace "non-immunoglobulin moiety" with "cytokine." Accordingly, Applicants respectfully request the rejection be reconsidered and withdrawn.

Claim rejections under 35 U.S.C. § 112, first paragraph, written requirement

Claims 1-11, 16-19, 23 and 24 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office action alleges that the present specification does not reasonably convey to a person of ordinary skill in the art that Applicants had possession of the claimed invention at the time of filing because it is not known if all the molecules of the present invention are less immunogenic than a variable region of a mouse anti-GD2 antibody.

Applicants submit that the present application provides sufficient support throughout the specification that the antibody variable regions of the present invention are less immunogenic than a variable region of a mouse anti-GD2 antibody (*see*, *e.g.*, pages 6-7, paragraphs 22 to 29). Nevertheless, in order to advance the prosecution of the application, Applicants have amended independent claims to delete the recitation of "wherein the antibody variable region (i) is capable of binding to human GD2 and, (ii) when administered to a human patient, is less immunogenic than a variable region of a mouse anti-GD2 antibody." The recited amino acid sequences in amended claims are fully supported in the specification. Accordingly, Applicants respectfully request the rejection be reconsidered and withdrawn.

In addition, the Office action alleges that the specification fails to provide adequate support for the term "non-immunoglobulin moiety" recited in claims 16 and 23. Without acquiescing to the rejection, and solely to advance prosecution, Applicants have cancelled claim 16 without prejudice and amended claim 23 to replace "non-immunoglobulin moiety" with "cytokine." Written support for "cytokine" is found throughout the specification, for example, on page 12, paragraph 45. Accordingly, Applicants respectfully request the rejection be reconsidered and withdrawn.

Claim rejections under 35 U.S.C. § 102

Claims 1-11 and 16-19 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Lode *et al.* (J. Clin. Invest. 2000, 105(11):1623-1630). Claims 1-11 and 16-19 are also rejected under 35 U.S.C. § 102(e) as being anticipated by Gillies *et al.* (U.S. Publication No. 20030166877). Applicants traverse the rejections to the extent it is maintained over the claims as amended.

With regard to Lode *et al.*, the Office action asserts that, even though Lode *et al.* does not specifically disclose the sequence of hu14.18-IL-2, it comprises, absent any evidence to the contrary, the sequence of SEQ ID NO:1, SEQ ID NO:2, and fusion protein of the instant invention comprising IL-2. The Office action further asserts that Gillies *et al.* anticipates the claims for the same reasons. Applicants respectfully disagree with the Office action. It is well established that anticipation under 35 U.S.C. § 102 requires that each and every element of the claimed invention must be identically disclosed or described in a single prior art reference. *In re* Bond, 910 F.2d 831, 832, 15 U.S.P.Q.2d (BNA) 1566, 1567 (Fed. Cir. 1990) (quoting Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 677, 7 U.S.P.Q.2d (BNA) 1315, 1317 (Fed. Cir. 1988).

Amended independent claim 1 recites "[a]n antibody variable region comprising the amino acid sequence set forth in SEQ ID NO:1." Amended independent claim 2 recites "[a]n antibody variable region comprising the amino acid sequence set forth in SEQ ID NO:2." Amended independent claim 6 recites "[a]n antibody variable region comprising an amino acid sequence selected from the group consisting of amino acids 1-23 of SEQ ID NO:1, amino acids 1-25 of SEQ ID NO:2, and amino acids 67-98 of SEQ ID NO:2." As the Office action notes, Lode *et al.* does not teach any of the sequences set forth in claims 1, 2 or 6. Similarly, Gillies *et al.* does not teach any of the sequences set forth in claims 1, 2 or 6. Because neither reference discloses the claimed sequences, neither reference discloses each and every element of the claimed invention. Moreover, because neither reference discloses the claimed sequences, neither reference provides enabling teachings of the claimed invention. Therefore, neither reference anticipates independent claims 1, 2 or 6 or any claims (*e.g.*, 3-5, 7-11 and 16-19) dependent therefrom.

Applicants respectfully request reconsideration and withdrawal of the rejections.

Claim rejections under 35 U.S.C. § 103

Claims 23 and 24 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Lode *et al.* in view of Gillies *et al.* (WO 01/10912 A1). Applicants traverse the rejection to the extent it is maintained over the claims as amended.

Claims 23 and 24 indirectly depend from independent claim 6, therefore, incorporate by reference all limitations recited in claim 6. As discussed above, amended independent claim 6 recites "[a]n antibody variable region comprising an amino acid sequence selected from the group consisting of amino acids 1-23 of SEQ ID NO:1, amino acids 1-25 of SEQ ID NO:2, and amino acids 67-98 of SEQ ID NO:2." Lode *et al.* does not teach or suggest an antibody variable region comprising any of the sequences as set forth in claim 6. Gillies *et al.* (WO 01/10912 A1) does not correct the deficiency of Lode *et al.* because Gillies *et al.* does not teach or suggest any of the sequences as set forth in claim 6. Therefore, even if, *arguendo*, the disclosures of Lode *et al.* and Gillies *et al.* were combined, the combined teachings would not have suggested to one of ordinary skill in the art to make an antibody variable region with any of the sequences as claimed in claim 6. Accordingly, Applicants submit claim 6 and claims 23 and 24 dependent therefrom are novel and unobvious over Lode *et al.* and Gillies *et al.*, either alone or in combination.

Applicants respectfully request reconsideration and withdrawal of the rejection.

Double Patenting

Claims 6, 16-19, 23 and 24 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-5 and 13 of co-pending Application No. 11/040,071. Applicants request that the provisional double patenting rejection be held in abeyance until the presence of otherwise-allowable subject matter is acknowledged.

CONCLUSION

Claims 1-11, 17-24, and 45-48 are pending and presented for consideration. The Examiner is invited to contact the undersigned to discuss any outstanding issues. Early favorable action is respectfully requested.

Respectfully submitted,

Date: September 23, 2005
Reg. No. 51,551

Fangli Chen, Ph.D.
Agent for Applicants
Kirkpatrick & Lockhart Nicholson Graham LLP
75 State Street
Boston, Massachusetts 02109

Tel. No.: (617) 261-3198
Fax No.: (617) 261-3175
Customer Number: 022832